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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,361	02/18/2000	Marc Howard Spinoza	604-540	8242
23117	7590	07/13/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/506,361	SPINOZA, MARC HOWARD	
Examiner	Art Unit		
Catherine S. Williams	3763		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 4/21/05.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 13, 15-20, 31-36, 39, 47, 49, 52-69 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 13, 15-16, 18-20, 31, 34-36, 39, 47, 49, 52-53, 55-58, 62-68 is/are rejected.

7)  Claim(s) 17, 32, 33, 54, 59-61, 69 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

The amendment filed 4/21/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the collar being a ring.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63,65 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The collar being a ring was not described in the specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13,15-16,18-20,36,47,49,52-53,55-58 and 62-67 are rejected under 35

U.S.C. 102(b) as being anticipated by Potter et al (US Pat# 4,867,154). Potter discloses an endotracheal tube stabilizing device that includes a tubular sleeve fastener (68) of variable length configured when lengthened to grip a tube (11) which has a lumen and is configured to transport fluid to or from a patient. See figure 1. While the sleeve (68) is helically formed around the tube (11), when looked at in its entirety the sleeve (68) takes on a tubular appearance because it has tubular dimensions (i.e. diameter and height). See figure 14. The sheath (68) is capable of gripping tube (11). See 7:15. While the specification does not disclose and the drawings do not show the sheath gripping the tube when lengthening, the sheath is considered capable of lengthening and gripping the tube. Clearly the sheath (68) grips the tube when the tube is moving away from the patient and pulls the sheath with it. See figure 14. The tube, by pulling away from the patient, lengthens the sheath and the sheath then grips the tube. As one can see in figure 14, when the sheath is shortened (see figure 14) the tube can freely slide along the length of the sheath. Attachment means includes loops (4,8,18) of harness (2) attach the sheath to the patient via pad (20). The sheath includes a collar (19) in the form of a ring.

Claims 13, 31,34-36 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Kite et al (US Pat# 4,754,685). Kite discloses an abrasion resistant braided (spiral weave) tubular sleeve for use as protective sleeving over tubes such as pipes, conduits and air hoses. See 1:5-10,1:16 and 4:54. The tube radially expands when axially compressed. See 1:33+ and 2:34-40. Once axially compressed the sleeve can be fitted (slide) over top hoses and other tubular

structures. The tube then extends axially (lengthens) to radially compress (grips) over the hose. See 2:39. The braided structure of the sleeve has a foraminous wall (open weave). See figure 1. The braid is made from polyester fiber. See 2:43.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kite et al or Potter et al. Both patents independently meet the claim language as described above but both fail to include instructions for use.

At the time of the invention, it would have been obvious to incorporate instructions independently into both devices above. Instructions are well known not only in the art but in most products for sale or use in this country. Instructions are a valuable tool manufacturers use to enable the end user to properly and safely use the device. The motivation for incorporating instructions into either device above would have been to enhance the safety of the user of the device.

***Allowable Subject Matter***

Claims 17,32-33,54,59-61 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 4/21/05 have been fully considered but they are not persuasive.

Regarding the Potter reference, Applicant argues that the coiled wire in the Potter reference cannot be considered a tubular sleeve because the coiled wire has very large gaps between the turns of the coil. Applicant also asserts that the claimed tubular sleeve can impart an evenly distributed force over the elongate portion of the tube.

The coiled wire of Potter is a tubular sleeve in the same way that element 20 of the instant invention is a tubular sleeve. Attention is drawn to figures 4(a) and 4(b), page 11 lines 17-19 and page 12 lines 3-16 of the instant application. The noted text describes how the tubular sleeve has openings which can be expanded or contracted and the figures clearly show this feature of the tubular sleeve. Since applicant's tubular sleeve includes openings but is still claimed as a tubular sleeve, then the prior art tubular sleeve having openings does not negate its being considered a tubular sleeve.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the tubular sleeve imparts an evenly distributed force on the tube) are not recited in the rejected

claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also argues that Potter does not teach lengthening the tubular sleeve to grip the tube. However, the claim recites “configured when lengthened to grip the tube” which is a functional recitation. The prior art only has to be capable of performing this function even if not specifically shown in the prior art. Since the tubular sleeve of Potter is a coil, the coil structure itself is a configuration that is capable of lengthening. When the coil lengthens it will automatically contract. At some point, the coil will be pulled so far that the contraction will result in the coil contacting the tube.

Applicant also states that the coil of Potter does not grip the tube because spikes or barbs really grip the tube. However, the Fig 3 is not relied on in the above rejection; therefore, the arguments regarding the barbs is moot. Regarding the spikes 71, these elements are part of the coil and therefore the prior art structure still reads on the claim limitations.

Regarding the Kite reference, Applicant argues that Kite does not teach a fastener for securing a tube to a patient and the tube itself.

The issue seems to be whether the prior art tubular sleeve can be considered a fastener. Applicant’s claim 13 recites a fastener in the preamble and since that term occurs in the preamble it is given limited patentable weight. Additionally, the claim recites “fastener... comprising a tubular sleeve” and the body of the claim does not recite any additional structure for further defining the fastener. Therefore according to the claim, the fastener is a tubular sleeve and nothing more. Kite clearly teaches a tubular sleeve; therefore, Kite teaches a fastener according

to the claim language. If applicant is relying on additional structure to define the fastener, then it is suggested that those structures be included in claim 1.

Applicant also argues that Kite does not teach the tube itself. Attention is drawn to the rejection above and column 1 line 5-10 of Kite which clearly teaches that the tubular sleeve can be placed over tubes such as pipes, conduits, and air hoses.

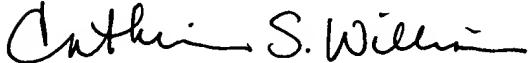
In response to applicant's argument that the Kite does not teach a fastener "for securing said tube to a patient", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). As stated above, the claim recites a fastener comprising a tubular sleeve and nothing more. Therefore, it is the tubular sleeve alone that is capable of "securing said tube to a patient". In the same way that the claimed tubular sleeve is capable of securing said tube to a patient, the prior art is capable of securing a tube to a patient. It is suggested that if additional structure is relied on for securing the tube to the patient that structure should be claimed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams  
July 5, 2005



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